James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DECLARATION OF ROBERT CARR IN SUPPORT OF DEFENDANTS' MOTION TO SEAL DOCUMENTS FILED IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT REGARDING PREEMPTION

(Assigned to the Honorable David G. Campbell)

I, Robert Carr, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following is true and correct to the best of my knowledge and belief:

1. I am over 18 years of age and am competent to testify about the matters contained herein. The statements contained herein are based on my personal knowledge and

upon the basis of the documents maintained by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard") in the regular course of business.

2. I am presently employed as the Vice President of International at Bard Peripheral Vascular, Inc. ("BPV") a subsidiary of C. R. Bard, Inc. ("C. R. Bard"). Until October 2015, I was Senior Director of Research and Development at BPV. Bard manufactures and distributes inferior vena cava ("IVC") filters and has manufactured and distributed the Recovery® Filter, G2® Filter, G2® Express Filter, G2®X Filter, Eclipse® Filter, Meridian® Filter, and Denali® Filter (collectively, "Bard IVC Filters"), each of which is a medical device cleared by the Food and Drug Administration ("FDA") indicated for treatment of blood flow problems posing the risk of pulmonary embolism. Before joining BPV in 2002, I was employed by Nitinol Medical Technologies ("NMT"), where I was also responsible for that company's research and development of IVC filters.

3. This declaration is based upon my personal knowledge and review of certain business records prepared and maintained in the ordinary course of business of Bard and of certain public records that set out FDA's regulatory activities concerning Bard's IVC Filters. I could and would competently testify to the matters set forth herein if called as a witness in this matter. As part of and during the course of my work with Bard and NMT, I have become familiar with documentation and records associated with the design, development, manufacture, regulatory compliance, and testing (including clinical testing) of the Bard IVC Filters.

a. The documentation and records include, for example, 510(k) submissions, IDE submissions, and other materials sent to FDA, as well as contact reports and email communications with the FDA, which detail Bard's product development and regulatory compliance activities of Bard's IVC Filters.

b. The documentation and records also include internal documents prepared by the FDA, a public federal agency. These records or statements of a public office detail the agency's investigation and regulatory review activities of Bard's regulatory compliance and product development activities concerning Bard's IVC Filters.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

4. As part of and during the course of my work with Bard, I have become familiar with Bard's record-keeping procedures. I have personal knowledge of the roles and responsibilities of Bard's employees responsible for this record-keeping process. The business documents referenced herein were prepared and maintained in the ordinary course of Bard's business, and it was the regular practice of Bard to make such records. These documents were prepared at or near the time of the events they record by persons with knowledge of the recorded events or from information transmitted by persons with knowledge of the recorded events.

5. Bard or its affiliates are engaged in the development, design, manufacturing, and distribution of medical devices, including the Bard Filters. Many documents involving the Bard IVC Filters are confidential and are maintained as such by Bard for the reasons listed below.

6. The medical device business for IVC filters is a highly technical and sophisticated industry. It is also a highly competitive industry in which each company carefully guards its company documents, data, systems, processes, research and development, analysis, marketing strategies and trade secrets from competitors.

7. As part of and during the course of my work with Bard, I have become familiar with Bard's efforts to protect its trade secret and confidential proprietary information and documents. This information is maintained internally at Bard and distributed to employees who need to know the information to perform their duties. It is not available outside the company. Outside physician consultants working with the company who have access to this information sign confidentiality agreements. Additionally, Bard has always sought a Protective Order or Confidentiality Agreement during the course of civil lawsuits in order to protect their confidential, proprietary and trade secret information

8. As part of and during the course of my work with Bard and NMT (before Bard acquired the NMT filter product line), I have become familiar with documentation

and records associated with the design, development, manufacture, regulatory compliance, and testing (including clinical testing) of the Bard IVC Filters.

9. I am familiar with the exceptions to the Freedom of Information Act ("FOIA"). Specifically FOIA recognizes an exception for trade secrets, and confidential commercial and financial information. When FDA makes a production, it redacts confidential and trade secret information provided by medical device companies such as Bard including: drafts of documents; testing protocols; test methods, results and analysis; design protocols; DFMEA (Design Failure Modes and Effects Analysis); engineering drawings; and other documents created during the design of a medical device.

10. Attached as Exhibit "A" is a chart identifying documents from Bard's extensive communications with and submission to the FDA relating to its IVC filters that are redacted. Bard had made FOIA requests for these documents, and the redacted information in the documents identified on Exhibit "A" is confidential trade secret, commercial and financial information that was redacted exactly as they were redacted and produced by FDA in the FOIA response. The redacted information consists of: drafts of documents; testing protocols; test methods, results and analysis; design protocols; DFMEA (Design Failure Modes and Effects Analysis); engineering drawings; and other documents created during the design of the filter discussed in those documents.

11. Attached as Exhibit "B" is a chart identifying documents from Bard's extensive communications with and submission to the FDA relating to its IVC filters that are redacted. Bard did not have a FOIA production from FDA for these documents, but the redacted information in the documents identified on Exhibit "B" is confidential trade secret, commercial and financial information that was redacted consistent with the types of redactions made by FDA in response to a FOIA request for similar submissions from Bard. The redacted information consists of: drafts of documents; testing protocols; test methods, results and analysis; design protocols; DFMEA (Design Failure Modes and Effects Analysis); engineering drawings; and other documents created during the design of the filter discussed in those documents.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

12. The redacted information contained in the documents referenced in Exhibits "A" and "B" required years for Bard to develop and is Bard's critical business information which is not made public by Bard.

13. The redacted information contained in the documents referenced in Exhibits "A" and "B" would be of economic value to Bard's competitors. Moreover, such value would extend not only to manufacturers of other IVC filters, but also to manufacturers of other medical devices, as the value and utility of this information is not limited to IVC filters.

14. Bard invests very substantial sums of money in medical device research, testing (including clinical testing), development, design, analysis, regulatory compliance, evaluation, and marketing. If the information Bard has developed over the years pertaining to the Bard IVC Filters was obtained by its competitors, it would give an unfair economic advantage to those competitors.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct.

Executed on this 28th day of August, 2017.

Robert Carr

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Exhibit A

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Documents Redacted Exactly as Produced by FDA Pursuant to a FOIA Request

A. Exhibits to Exhibit A Declaration of Robert Carr In Support of Defendants' Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Bates No.	Description
43.	03/02/2005	BPV-17-01-00125335 through 125415	BPV's Modified Recovery Filter Special 510(k) (K050558)
45.	03/29/2005	FDA_PRODUCTION_ 00000206 through 22045	Internal FDA memo re Modified Recovery (K050558)
46.	03/30/2005	BPV-17-01-00125312 through 125314	Letter FDA to BPV re Modified Recovery (K050558)
58.	07/28/2005	BPV-17-01-00125220 through 125222	Letter FDA to BPV re AI re Modified Recovery (K050558)
60.	08/10/2005	BPV-17-01-00125616 through 125633	Letter BPV to FDA Responses to AI re G2 (K050558)
104.	03/07/2008	BPV-17-01-00130498 through 130730	BPV's G2 Express Filter Special 510(k) (K080668)
105.	04/08/2008	BPV-17-01-00130470 through 130473	Letter FDA to BPV re AI Demand re G2 Express (K080668)
106.	05/05/2008	BPV-17-01-00131255 through 131261	Letter BPV to FDA Request 30 day extension re G2 Express (K080668)
108.	05/08/2008	BPV-17-01-00130268 through 130441	Letter BPV to FDA Responses to AI Demand re G2 Express (K080668)
109.	06/06/2008	BPV-17-01-00130460 through 130463	Letter BPV to FDA Responses to AI Demand re G2 Express (K080668)
110.	06/25/2008	BPV-17-01-00117271 through 117272	Conference FDA and BPV re AI Demand re G2 Express (K080668)
111.	06/26/2008	BPV-17-01-00130442 through 130448	Letter BPV to FDA Request 30 Day Extension re G2 Express (K080668)
113.	07/02/2008	BPV-17-01-00117260 through 117783	Letter BPV to FDA Responses re AI Demand re G2 Express (K080668)
121.	11/23/2009	BPV-17-01-00116991 through 117153	BPV's Eclipse Filter System Special 510(k) (K093659)
123.	12/17/2009	BPV-17-01-00145607 through 145616	Letter BPV to FDA re Responses to FDA AI Demand re Eclipse (K093659)
125.	05/20/2010	BPV-17-01-00171679 through 171793	BPV's Eclipse Filter Special 510(k) (K101431)
127.	06/21/2010	BPV-17-01-00145617 through 145633	Letter BPV to FDA re Responses to FDA AI Demand re Eclipse (K101431)

Exhibit B

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Documents Filed Redacted Consistent with FOIA

A. Exhibits to Exhibit "A" Declaration of Robert Carr In Support of Defendants' Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Bates No.	Description
3.	02/10/2000	BPV-17-01-00058907 through 58930	Conference FDA and NMT re Recovery (K993809) Test methods and results
8.	08/12/2002	BPV-17-01-00059159 through 59193	Conference IMPRA and FDA re Recovery (K022236)
32.	01/10/2005	BPV-17-01-00043382 through 43402	Conference FDA and BPV re DDL and Recovery Retrievable (K031328)
34.	01/22/2005	BPVE-01-00303306 through 303318	Email from BPV to FDA re DCL and Recovery Retrievable (K031328)
47.	04/19/2005	FDA_PRODUCTION_ 00000193 through 201	BPV's Informal Responses to FDA AI Letter re Modified Recovery (K050558)
54.	6/03/2005	BPV-17-01-00125416 through 125616	Letter BPV to FDA re Modified Recovery conversion Traditional 510(k) (K050558)
61.	08/19/2005	BPVE-01-00155084 through 155088	Email BPV to FDA re G2 (K050558)
62.	08/22/2005	BPVE-01-00155392 through 155396	Email BPV to FDA re G2 (K050558)
68.	06/03/2005	BPV-17-01-00125226 through 125285	Email BPV to FDA re proposed IDE G2 Everest Study
69.	07/08/2005	BPV-17-01-00122544 through 122829	BPV's original IDE submission re G2 Everest Study (G050134) Test methods and results
74.	10/21/2005	BPVE-01-00275704	Conference FDA and BPV re G2 Everest Study (G051034) and future submission
79.	07/11/2006	BPV-17-01-00123071 through 123152	Letter BPV to FDA re G2 Everest Study (G051304) IDE Supplement
85.	10/25/2007	BPV-17-01-00123498 through 123562	Letter BPV to FDA re Responses to FDA re G2 Everest Study (G051304) Test methods and results
89.	9/19/2005	BPV-17-01-00125658 through 125749	BPV's G2 Filter - Jugular Subclavian Delivery Kit Special 510(k) (K052578)
91.	10/13/2005	BPV-17-01-00046358 through 46362	Email FDA to BPV re G2 Filter - Jugular Subclavian Delivery Kit (K052578)
94.	10/14/2005	BPV-17-01-00048142 through 48144	Letter FDA to BPV re G2 Filter - Jugular Subclavian Delivery Kit (K052578)
95.	10/25/2005	BPV-17-01-00125782 through 125876	Letter BPV to FDA Responses to FDA AI Demand re G2 Filter - Jugular (K052578)

Ex. No.	Date	Bates No.	Description
			Test methods and results
97.	11/16/2005	BPV-17-01-00125893 through 125923	Letter BPV to FDA Responses to FDA AI Demand re G2 Filter - Jugular (K052578) Test methods and results
99.	09/25/2006	BPV-17-01-00125963 through 126062	BPV's G2 Filter - Femoral Delivery Kit Special 510(k) (K062887)
102.	10/31/2007	BPV-17-01-00123629 through 125197	BPV's G2 Filter Retrievable Traditional 510(k) (K073090)
115.	08/12/2008	BPV-17-01-00131320 through 131596	BPV's G2X Filter Special 510(k) (K082305) Redacted consistent with FOIA exceptions
118.	09/29/2008	BPV-17-01-00130734 through 130838	Letter BPV to FDA re Responses to FDA AI Demand re G2X (K082305) Test methods and results

B. Exhibits to Exhibit B Declaration of John D. Van Vleet In Support of Defendants' Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Bates No.	Description
1.	08/14/2009	BPV-17-01-00171823 through 171824	FDA Contact Report (Eclipse and Platinum Pre IDE)
3.	12/03/2009	BPVEFILTER-08-00026072 through 26125	Meridian Pre-IDE Meeting Request Test methods and results
4.	01/08/2010	BPV-17-01-00171850 through 171853	(Meridian Pre IDE) Test methods and results
5.	08/31/2010	BPV-17-01-00150192 through 151045	Meridian Jugular Subclavian Delivery Kit Traditional 510(k) (K102511) Redacted consistent with FOIA exemptions
6.	10/26/2010	BPVE-01-01977697 through 1977704	Letter from FDA to BPV re Meridian Jugular (K102511) Test methods and results
7.	11/12/2010	BPV-17-01-00171872 through 171873	(Meridian) Test methods and results

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Ex. No.	Date	Bates No.	Description
8.	11/16/2010	BPVE-01-01404251 through 1404291	Email to FDA enclosing fatigue testing info re Meridian Test methods and results
10.	12/27/2010	BPVEFILTER-01-01201729 through 1201779	Letter from BPV to FDA re Meridian Jugular (K102511) Test methods and results
11.	12/27/2010	BPVEFILTER-11-00002394 through 2960	Appendices to Letter to FDA Redacted consistent with FOIA exemptions
12.	02/01/2011	BPVEFILTER-01-00016497 through 16501	Letter from FDA to BPV re Meridian Jugular (K102511) Test methods and results
13.	02/10/2011	BPV-17-01-00171836 through 171838	FDA Contact Report (Meridian) Test methods and results
14.	02/17/2011	BPV-17-01-00171841 through 171844	(Meridian) Test methods and results
15.	02/22/2011	BPVEFILTER-01-01853704 through 1853705	Email with FDA re chromosomal aberration testing (Question 3 from Feb. 1 letter) Test methods and results
16.	05/17/2011	BPV-17-01-00171857 through 171864	(Meridian) Test methods and results
17.	05/17/2011	BPVEFILTER-01-00136505	PPT to FDA re Meridian Test methods and results
18.	05/20-23/2011	BPVEFILTER-08-00065051 through 65053	Email chain re deficiencies 8 and 9 Test methods and results
19. a.	05/23/2011	BPVEFILTER-08-00076994 through 77147	Letter to FDA re Meridian FDA Questions Feb. 1, 2011 Nos 1-7, 10-13 Test methods and results

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Ex. No.	Date	Bates No.	Description
19.b.	05/23/2011	BPVEFILTER-08-00077067	Letter from BPV to FDA (Appendix 6) Produced in Native Format Test methods and results
20.	06/16/2011	BPVEFILTER-01-01138842 through 1138951	Email from custodial file of Joni Creal with Appendix 1-6 Test methods and results
21.	06/22/2011	BPV-17-01-00171877 through 171879	(Meridian) Test methods and results
22.	06/27/2011	BPVEFILTER-08-00075953 through 76043	Email from custodial file of Joni Creal with Appendix 1 & 2
23.	06/27/2011	BPVEFILTER-08-00074784 through 74827	Email from custodial file of Joni Creal with Appendix 3-5
24.	06/27/2011	BPVEFILTER-08-00085241 through 85294	Email from custodial file of Joni Creal with Appendix 6 & 7
25.	06/27/2011	BPVEFILTER-08-00083555 through 83592	Email from custodial file of Joni Creal with Appendix 8 & 9
26. a.	06/27/2011	BPVEFILTER-08-00081986 through 82031	Email from custodial file of Joni Creal with Appendix 10 & 11
26.b.	02/10/2011	BPVEFILTER-08-00082031	Letter from BPV to FDA (Appendix 11) Produced in Native Format
27.	06/27/2011	BPVEFILTER-08-00080312 through 80407	Email from custodial file of Joni Creal with Appendix 12 & 13
28.	06/27/2011	BPVEFILTER-01-01156092 through 1156185	Email from custodial file of Joni Creal with Appendix 14 Part A
29.	06/27/2011	BPVEFILTER-35-00027113 through 27173	Email from custodial file of Joni Creal with Appendix 14 Part B
30.	08/17/2011	BPVEFILTER-08-00077841 through 77854	Email with FDA re Meridian IFU changes
32.	08/27/2011	BPV-17-01-00147141 through 147592	Femoral Delivery Kit Special 510(k) (K112497) (Vol. I & II) Redacted consisted with FOIA exemptions
34.	09/30/2011	BPV-17-01-00147598 through 147607	Letter from BPV to FDA re Meridian Filter System Response to FDA Questions